REMARKS/ARGUMENTS

Claims 1-5, 7-9, 33-40 and new claim 41 are under examination in this application. Claims are rejected under various grounds including anticipation, lack of written description and lack of patentable subject matter.

A new abstract is provided that meets the objection raised by the examiner.

The claims have been amended, per the examiner's suggestions, to call for an isolated and purified heptasaccharide having the formula GalNAc-a1,4-GalNAc-a1,4-[Glc-β1,3]GalNAc-a1,4-GalNAc-a1,4-GalNAc-a1,3-Bac, wherein Bac is 2,4-diacetamido-2,4,6-trideoxy-D-glucopyranose. In some cases the claimed heptasaccharide is linked to an amino acid or oligopeptide. Applicants submit that the rejection of claims under 35 U.S.C. 101 has been overcome and request that it be withdrawn.

Claims calling for the type of bacterium from which the heptasaccharide is produced have been amended to specify that the bacterium is selected from *C. jejuni* and *C. coli*

Applicants submit that the rejection of claims under 35 U.S.C. 112 has been overcome and should be withdrawn.

Claims 1, 2, 4-5, 33 and 35-36 stand rejected as anticipated by Linton et al. in light of evidence provided by Szymanski et al. Applicants submit that the amendment of claims to be directed to an isolated and purified form of the designated heptasaccharide overcomes this rejection.

Linton et al. characterize glycoproteins expressed by *C. jejuni* and describe isolation of C. *jejuni* glycoproteins, both with and without their polysaccharide residues. However, Linton et al. do not describe any process that would yield the intact heptasaccharide described in the present application, either in isolated form or linked to a single amino acid or an oligopeptide.

At page 503, Linton et al. describe treating an extract from *C. jejuni* with enzymes to degrade the saccharide residue to permit isolation of the protein component of the glycoprotein, and separating the resulting protein component from the mixture with SDS-page

blotting. Enzymatic treatment of this type would remove the GalNAc residues of the heptasaccharide, one (or possibly more than one) residue at a time. This would not yield the intact, isolated heptasaccharide. Thus, the experiments described by Linton et al. would not have generated the heptasaccharide described in claim 1 as presently amended.

Linton et al. further describe at page 504, column 2 purification of a set of SBA binding proteins, from which the glycoprotein in question was identified. Those authors confirm that they isolated the protein portion from the polysaccharide residue, resulting in a loss of binding activity of the protein. However, Linton et al. do not describe any isolation or purification of the glycan portion of the glycosylated protein, nor removal of the intact glycan, either with or without a single amino acid or oligopeptide attached thereto. The excerpt cited by the Examiner (page 505, line 1) merely refers to characterization of the intact glycoprotein. In one important respect, however, this characterization was incorrect.

Linton et al. state that the GalNAc residue is linked to a serine or threonine of the glycoprotein. Linton et al. assumed that the GalNAc residue would be linked directly to a serine or threonine, presumably because in previously described animal glycoproteins, GalNAc was always attached to a Ser or Thr. However, as noted by the present inventors, the heptasaccharide is in fact linked to the protein at an Asn (see page 19 of the specification). The present inventors' discovery of this aspect permitted them to recognize that one could isolate the heptasaccharide, either linked to Asn (by cleaving the Asn from the peptide) or directly, without going through the oligopeptide (see Example 5 of the specification). Example 5 also describes a method to cleave the heptasaccharide directly from the glycoprotein, for example using hydrazine, to yield the isolated heptasaccharide.

Such methods are neither taught nor suggested by Linton et al. That reference provides no motivation to isolate the saccharide: the work focused on the protein component of the glycoprotein, and the authors provided no suggestion that one could isolate the glycan residue - or that this would be of any particular utility - nor did they suggest any methods by which one could isolate it.

Applicants submit that degrading of the glycan portion of the glycoprotein and

isolating or characterizing the resulting protein is fundamentally different from isolating and purifying the glycan moiety. Thus, claim 1 as now amended describes subject matter that was not made or disclosed by Linton et al., nor would the skilled person be enabled to produce the claimed invention by following the teachings of Linton et al. without exercising inventive ingenuity.

Similarly, Szymanski et al described obtaining the intact glycoprotein, in which the glycosyl moiety may be immunodominant in comparison with the protein portion. The glycoprotein was obtained by isolating the newly identified PGL gene, and expressing the protein translated therefrom. Significantly, Szymanski et al. did not purify or isolate the glycan portion of the glycoprotein. Rather, the glycoprotein was left intact. Accordingly, Szymanski et al. do not inherently describe the purified and isolated glycan, as now claimed, or this glycan linked to a single amino acid or oligopeptide.

It is thus apparent that neither Szymanski et al. nor Linton et al. described isolating or purifying either the glycan in isolated and purified form or that heptasaccharide linked to an amino acid or oligopeptide.

The rejection of these claims as anticipated by Linton et al. and Szymanski et al. therefore should be withdrawn.

Claims 1 - 5 and 33 - 36 are rejected as anticipated by Szymanski et al. in light of evidence provided by Guerry et al.

Szymanski et al. is discussed above. Guerry et al. do not provide any additional information that shows that Szymanski et al. isolated or purified the claimed heptasaccharide.

This is implicitly recognized by Guerry et al., in their discussion of the Szymanski et al. paper. At page 1, column 2, they recognize that Szymanski et al. isolated the glycoprotein, which included the glycan subsequently shown by the current inventors to be a heptasaccharide. However, Guerry et al. fail to state that Szymanski et al. had prepared and isolated or purified the polysaccharide component of the glycoprotein. The present invention, on the other hand, represents the first time that the claimed heptasaccharide has been isolated and purified. As well, the optional form in which heptasaccharide is linked to a single amino acid or

an oligopeptide also represents the first such isolation and purification of this compound. The prior art discloses the glycoprotein, which is a different compound from the claimed heptasaccharide (optionally linked only to a single amino acid or oligopeptide).

Claims are variously rejected as being anticipated Bay et al., Pugia et al., Nilsson et al., Messner et al., Gutnick et al., and Kaplan et al. These references were discussed in the previous response. None of them discloses the claimed isolated and purified heptasaccharide. These rejections should likewise be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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